IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA

RALPH T. MOTES, JR.	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No.:**
	)	
ELI LILLY AND COMPANY,	)	
	)	
Defendant.	)	

COMPLAINT

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1. This is an action for personal injuries and damages suffered by Plaintiff Ralph T. Motes, Jr. ("Plaintiff") as a direct and proximate result of Eli Lilly and Company's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of tadalafil tablets sold under the brand name Cialis® ("Cialis").

PARTIES

2. Plaintiff Ralph T. Motes, Jr. is and was at all relevant times an adult resident citizen of the County of Wakulla, State of Florida.

3. Defendant Eli Lilly and Company (hereinafter "Defendant") is a corporation organized and existing under the laws of the State of Indiana. Defendant maintains its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly's registered agent is National Registered Agents, Inc., 150 West Market Street, Suite 800, Indianapolis, IN 46204.

4. At all times mentioned herein, Defendant engaged in interstate commerce, including commerce within the Northern District of Florida, in the advertisement, promotion, marketing, distribution, and sale of Cialis.

JURISDICTION AND VENUE

5. This Court has jurisdiction over Defendant and this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant and because the amount in controversy between Plaintiff and Defendant exceeds $75,000.00, exclusive of interest and costs.

6. This Court has personal jurisdiction over this Defendant because Defendant maintains significant contacts with this judicial district by virtue of conducting business within the district.

7. Venue is proper within this district and division pursuant to 28 U.S.C. § 1391, as Plaintiff resides in this district. Furthermore, Defendant marketed, advertised, and distributed Cialis in this judicial district, thereby receiving substantial financial benefit and profits from the dangerous product in this district.

FACTUAL BACKGROUND

A. Background

8. On November 21, 2003, the U.S. Food and Drug Administration approved new drug application ("NDA") 021368 from Lilly ICOS LLC for the manufacture and sale of tadalafil.[1]

9. Tadalafil, sold under the brand name Cialis, is an oral tablet prescribed to men with erectile dysfunction.

10. Erectile dysfunction is the medical designation for a condition in which a man cannot achieve or maintain an erection sufficient for satisfactory sexual activity. Since reaching and maintaining an erection involves an individual's brain, nerves, hormones, and blood vessels, any condition that interferes with any of these functional areas of the body may be causally related to an individual's erectile dysfunction. These problems become more common with age, but erectile dysfunction can affect a man at any age.

11. Cialis treats erectile dysfunction by inhibiting the secretion of phosphodiesterase type 5 ("PDE5"), an enzyme responsible for the degradation of

[1] The initial FDA approval for tadalafil was issued to the entity Lilly ICOS LLC. From 1998 to 2006, Eli Lilly and ICOS Corporation were partners in the joint venture known as Lilly ICOS LLC. This joint venture was responsible for the manufacture, marketing, and sale of Cialis from the drug's FDA approval in 2003 until Eli Lilly acquired ICOS Corporation in October of 2006. Press Release, Eli Lilly and Company, Lilly Announces Acquisition of ICOS Corporation (Oct. 17, 2006), https://investor.lilly.com/releasedetail.cfm?ReleaseID=214900. Plaintiff did not begin taking Cialis until after the acquisition, rendering the entity Lilly ICOS LLC relevant only for explanatory purposes here.

cyclic guanosine monophosphate ("cGMP"). When the cGMP is not degraded by the PDE5, smooth muscles in the corpus cavernosum relax; this, in turn, permits an inflow of blood to the corpus cavernosum, creating an erection.

12. The National Institutes of Health estimate that erectile dysfunction affects as many as thirty million men in the United States.[2]

13. Since Cialis's FDA approval in 2003, Defendant has engaged in a continuous and expensive multimedia advertising campaign to market Cialis to men worldwide as a symbol of regaining and enhancing one's virility.

B. Prevalence of Cialis in Market

14. In 2012, Cialis was the second largest drug in the global market of erectile dysfunction drugs accounting for over $1,926,000,000 in revenue.

15. In its 2013 Annual Report, Eli Lilly reported revenue exceeding $2,159,000,000 from worldwide sales of Cialis, a 12% increase in sales from 2012 to 2013.

16. Upon information and belief, as of May 2014 approximately 45 million men have taken Cialis.

C. Defendant's Knowledge of Defect

17. Unbeknownst to most Cialis users, and not mentioned in any of the advertising proliferated by Defendant, recent studies have shown that the cellular

[2] NIH Consensus Development Panel on Impotence (July 7, 1993).

activity providing the mechanism of action for Cialis may also be associated with the development and/or exacerbation of melanoma.

18. The American Cancer Society states that melanoma is "the most serious type of skin cancer."[3]

19. According to the National Cancer Institute, part of the National Institute of Health, melanoma is more likely than other skin cancers to spread to other parts of the body, thereby causing further tissue damage and complicating the potential for effective treatment and eradication of the cancerous cells.[4]

20. Several studies have linked the mechanism of action for Cialis to cell mutation cultivating melanomagenesis, or the creation of melanocytes which develop into melanoma.

21. A study published in 2011 found that treatment with a PDE5 inhibitor can promote melanoma cell invasion.[5] Specifically, by inhibiting PDE5, Cialis mimics an effect of gene activation and therefore may potentially function as a trigger for the creation of melanoma cells.

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[3] American Cancer Society, *Skin Cancer Facts*, last revised March 19, 2014, *available at*: http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts.
[4] National Cancer Institute, *Types of Skin Cancer*, last updated Jan. 11, 2011, *available at*: http://www.cancer.gov/cancertopics/wyntk/skin/page4.
[5] I. Aozarena, et al., *Oncogenic BRAF Induces Melanoma Cell Invasion by Downregulating The cGMP-Specific Phosphodiesterase PDE5A*, 19 CANCER CELL 45 (2011).

22. A 2012 study published in the Journal of Cell Biochemistry also found that PDE5 inhibitors were shown to promote melanin synthesis,[6] which may exacerbate melanoma development.[7]

23. On April 7, 2014, an original study ("the JAMA study") was published on the website for the *Journal of the American Medical Association Internal Medicine* which, in light of the previous studies, sought to examine the direct relationship between the use of PDE5 inhibitors and melanoma development in men in the United States.[8] The JAMA study was published in the journal's June 2014 edition.

24. Among 25,848 participants, the JAMA study reported that recent users of another PDE5 inhibitor, sildenafil citrate, at baseline had a significantly elevated risk of invasive melanoma, with a "hazard ratio" of 1.84; in other words, the study participants who had recently used sildenafil exhibited an 84% increase in risk of developing or encouraging invasive melanoma.[9]

25. The JAMA study did not specifically study the effects of Cialis use specifically on melanomagenesis, as Cialis had not yet been approved by the FDA

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[6] X Zhang, et al., *PDE5 Inhibitor Promotes Melanin Synthesis Through the PKG Pathway in B16 Melanoma Cells*, 113 J. CELL BIOCHEM. 2738 (2012).
[7] F.P. Noonan, et al., *Melanoma Induction by Ultraviolet A But Not Ultraviolet B Radiation Requires Melanin Pigment*, 3 NATURE COMMUNICATIONS 884 (2012).
[8] Wen-Qing Li, Abrar A. Qureshi, Kathleen C. Robinson, & Jiali Han, *Sildenafil Use and Increased Risk of Incident Melanoma in U.S. Men: A Prospective Cohort Study*, 174 JAMA INTERNAL MEDICINE 964 (2014).
[9] *Id*.

for treatment of erectile dysfunction. However, its central mechanism of action, the inhibition of PDE5, is the same mechanism of action that renders sildenafil citrate effective in treating erectile dysfunction.

26. On March 22, 2016, a study was published in *Cell Reports* which determined that PDE5 inhibition leads to increased tumor growth.[10] Specifically, melanoma cells express a cGMP pathway involving PDE5 and such pathway promotes MAPK signaling and melanoma cell growth and migration.[11] PDE5A (uninhibited) degrades cGMP, acting as a brake on the melanoma growth-promoting cGMP pathway.[12] Viagra, however, inhibits PDE5, thereby stopping it from degrading cGMP.[13] Without such degradation, Viagra leads to increased melanoma tumor growth.[14]

27. The *Cell Reports* study did not specifically study the effects of Cialis. However, its central mechanism of action, the inhibition of PDE5, is the same mechanism of action that renders Viagra effective in treating erectile dysfunction.

D. Consumer Expectations

[10] Dhayade et al., *Sildenafil Potentiates a cGMP-Dependent Pathway to Promote Melanoma Growth*, 14 Cell Reports 1 (2016).
[11] *Id.* at 3-4.
[12] *Id.* at 5-9.
[13] *Id.*
[14] *Id.*

28. Since the FDA's approval of Cialis in 2003, Eli Lilly has engaged in a continuous, expensive, and aggressive advertising campaign to market Cialis to men worldwide as a symbol of regaining and enhancing one's virility.

29. For example, none of the informational documents proliferated to patients using and physicians prescribing Cialis since the FDA's approval of the drug make any mention of the risk of melanoma associated with ingestion of Cialis.

30. As another example, none of the commercials or print advertisements promoting the prescription and use of Cialis, since its approval by the FDA, mention any melanoma-related risks associated with using the drug.

31. While designing and formulating Cialis, Defendant discovered or should have discovered that the drugs' mechanism of action, the inhibition of PDE5, also presented a significant risk of exacerbating melanoma.

32. Despite these significant findings, Defendant has made no efforts in its ubiquitous Cialis advertisements to warn users about the potential risk of developing melanoma that has been scientifically linked to these drugs.

33. Members of the general public had no plausible means through which they could have discovered the significant risk of melanomagenesis associated with PDE5 inhibition.

34. Prescribing physicians would not have had the same level of access to the research and development conducted by Defendant prior to its decision to manufacture Cialis for general public use.

35. Defendant failed to communicate to the general public that the inhibition of PDE5 inherently necessary to the efficacy of Cialis would also present a significant risk of one's development or exacerbation of cancerous cells.

36. For example, no individual prescribed to use Cialis would believe or be expected to know that his use of these drugs would expose him to an increased risk of developing melanoma or exacerbating the growth of melanocytes already present in his body.

37. Defendant expected or should have expected individuals who suffered from erectile dysfunction to ingest Cialis as a means to treat their condition.

38. Defendant expected or should have expected physicians treating erectile dysfunction to prescribe Cialis as a means to treat the condition.

39. The risk presented by ingesting Cialis would be present from the moment of manufacture; that is, the user would not need to change or alter the drug itself or the means by which it was ingested in order for the drug to carry the same risk of harm as described herein.

40. At all times relevant to this lawsuit, Defendant engaged in the business of researching, licensing, designing, formulating, compounding, testing,

manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Cialis for use among the general public.

41. At all times mentioned in this Complaint, Defendant's officers and directors participated in, authorized, and directed the production and promotion of Cialis when they knew, or with the exercise of reasonable care should have known, of the risk of developing melanoma associated with Cialis use. In doing so, these officers and directors actively participated in the tortious conduct which resulted in the injuries suffered by many Cialis users, including Plaintiff.

E. Risks and Benefits of Cialis Use

42. Erectile dysfunction is not fatal, nor does it present any related symptoms or characteristics harmful to one's physical health; however, it did provide the benefit of allowing men with erectile dysfunction to achieve and maintain an erection.

43. At all times relevant hereto, Cialis was useful to some members of the population; namely, men diagnosed with erectile dysfunction.

44. However, Cialis also encourages the development of melanoma in the body of a user, thereby placing them at a significant health risk.

45. Defendant manufactured, marketed and sold Cialis as a PDE5 inhibitor; however, the mechanism of action that made the drug effective in

treating erectile dysfunction simultaneously enhanced the risk of the user developing melanoma.

46. Through the testing and formulating of Cialis, and before the initiation of the drug's mass manufacture, Defendant knew or should have known in the exercise of ordinary care that the chemical reactions inherent to the mechanism of action for Cialis would present a cancer-related health hazard to potential future users.

47. The risk presented by the use of Cialis through PDE5 inhibition – a characteristic inherent to the drug's potential efficacy – was unquestionably far more significant than the benefit provided to its users.

48. Because the risk of using Cialis so greatly outweighs the benefits of such use, the drug presents an unreasonably dangerous risk when used in its intended condition.

F. Facts Regarding Plaintiff

49. Plaintiff began pharmaceutical treatment for erectile dysfunction in October of 2009, when his physician Dr. David Shafer prescribed Cialis.

50. Plaintiff continued to fill his Cialis prescriptions and take the drug regularly until December of 2012.

51. In August 2012, Plaintiff went to his primary care physician after noticing a lump in the right axillary area. His physician performed an ultrasound which showed signs of a bulky lymphadenopathy in the right axillary area.

52. On August 27, 2012, a right axillary lymph node excisional biopsy was performed. The biopsy was positive for malignancy consistent with Metastatic melanoma.

53. Since first being diagnosed with melanoma, Plaintiff has undergone multiple surgeries, CT scans, radiation, and chemotherapy.

54. Had Defendant properly disclosed the melanoma-related risks associated with Cialis, Plaintiff would have avoided the risk of developing melanoma by not using Cialis at all; severely limiting the dosage and length of its use; and/or more closely monitoring the degree to which the Cialis was adversely affecting his health.

55. Furthermore, had Defendant properly disclosed the melanoma-related risks associated with Cialis, Plaintiff's physician would have avoided such risk to his patient by not prescribing Cialis to him; severely limited the dosage he prescribed to Plaintiff; and/or closely monitored the length to which the Cialis was adversely affecting Plaintiff's health.

56. As a direct, proximate, and legal result of Defendant's negligent and wrongful conduct, and the unreasonably dangerous and defective characteristics of

the drug Cialis, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff endured not only physical pain and suffering but also economic loss, including significant expenses for medical care and treatment. Because of the nature of his diagnosis, he will certainly continue to incur additional medical expenses in the future. As a result, Plaintiff seeks actual and punitive damages from Defendant.

CAUSES OF ACTION

COUNT I
(Strict Liability – Defective Design)

57. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

58. Defendant has a duty to provide adequate warnings and instructions for Cialis, to use reasonable care to design a product that is not unreasonably dangerous to users, and to adequately test its product.

59. At all times relevant to this action, Defendant researched, designed, tested, manufactured, packaged, labeled, marketed, distributed, promoted, and sold Cialis, placing the drug into the stream of commerce.

60. At all times relevant to this action, Cialis was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendant in a condition that was defective and unreasonably dangerous to

consumers, including the Plaintiff.

61. Cialis is defective in its design and/or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

62. Cialis was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

63. Plaintiff used Cialis as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

64. Cialis was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiff, when it was used as intended and in a reasonably foreseeable manner.

65. Cialis was unreasonably dangerous and defective in design or formulation for its intended use in that, when it left the hands of the manufacturers and/or supplier, it posed a risk of serious injury which could have been reduced or avoided by the adoption of a feasible reasonable alternative design. There were safer alternative methods and designs for the like product.

66. Cialis was insufficiently tested and caused harmful side effects that outweighed any potential utility.

67. Cialis, as manufactured and supplied, was defective due to inadequate

warnings, and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of the clinical trials, testing and study.

68. Cialis as manufactured and supplied by the Defendant was defective due to inadequate post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of injuries from use and/or ingestion and acquired additional knowledge and information confirming the defective and dangerous nature of Cialis, Defendant failed to provide adequate warnings to the medical community and the consumers, to whom Defendant was directly marketing and advertising; and, further, Defendant continued to affirmatively promote Cialis as safe and effective.

69. In light of the potential and actual risk of harm associated with the drug's use, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that Cialis should not have been marketed in that condition.

70. As a direct and proximate cause of the Defendant's defective design of Cialis, including the lack of appropriate warnings, Plaintiff was prescribed and used the drug rather than alternative erectile dysfunction therapies with better and/or similar efficacy. Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

71. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT II
(Strict Liability – Failure to Warn)

72. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

73. While designing and formulating Cialis, Defendant discovered or should have discovered that the drug's mechanism of action, the inhibition of PDE5, also presented a significant risk of exacerbating melanoma.

74. Cialis was defective and unreasonably dangerous when it left the possession of the Defendant in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to the development and/or exacerbation of melanoma.

75. Information given by Defendant to the medical community and to consumers concerning the safety and efficacy of Cialis, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects.

76. Had adequate warnings and instructions been provided, Plaintiff would not have been prescribed or taken Cialis, and would not have been at risk of the harmful side effects described herein.

77. Neither Plaintiff, nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Cialis.

78. Defendant knew or had knowledge that the warnings that were given failed to properly warn of the increased risks of serious injury and/or death associated with and/or caused by Cialis.

79. Plaintiff, individually and through his prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of the Defendant.

80. Defendant expected Plaintiff, individually and through his prescribing physician, to rely upon the information contained in the subject product's package insert and other advertising and promotional materials.

81. Defendant had a continuing duty to warn Plaintiff and his prescribing physician of the risk of development and/or exacerbation of melanoma directly associated with Cialis use.

82. Safer alternatives were available that were just as effective and without the risks posed by Cialis.

83. As a direct and proximate result of Defendant's failure to warn Plaintiff or his physician of the significant melanoma-related risks associated with Cialis's mechanism of action, Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

84. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT III
(Failure to Test)

85. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

86. Through the testing and formulating of Cialis, and before the initiation of the drug's mass manufacture, Defendant knew or should have known in the exercise of ordinary care that the chemical reactions inherent to Cialis's mechanism of action would present a cancer-related health hazard to potential future users like Plaintiff.

87. Defendant failed to adequately test the safety of Cialis.

88. Had Defendant adequately tested relative efficacy of Cialis compared with other readily available, alternative erectile dysfunction therapies and disclosed those results to the medical community and the public, Plaintiff would not have purchased and used Cialis.

89. As a direct and proximate result of Defendant's failure to adequately test Cialis, Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

90. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IV
(Negligence)

91. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

92. Defendant owed Plaintiff a duty to exercise reasonable care when designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing, and/or selling Cialis.

93. At all relevant times to this action, Defendant owed a duty to properly warn Plaintiff, physicians, consumers, and the public of the risks, dangers and

adverse side effects of Cialis, including the increased risk of serious injury and death, when the drug was used as intended or in a way that Defendant could reasonably have anticipated.

94. Defendant breached its duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of Cialis, as set forth below.

95. Defendant failed to exercise due care under the circumstances and therefore breached this duty in numerous ways, including the following:

a. failing to research and test Cialis properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of Cialis;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Cialis which indicated serious risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of Cialis;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, promoting, advertising, distributing, and selling Cialis to physicians and consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Cialis and without proper instructions to avoid the harm that could foreseeably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting Cialis;

h. negligently continuing to manufacture, market, advertise, and distribute Cialis after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

j. failing to use due care in the design of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of Cialis;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Cialis, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Cialis for causing serious injury and/or death in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant of the need to change the drug's warnings or to withdraw it from the market altogether;

m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, Plaintiff's physicians, other consumers, the medical community, and the FDA;

n. failing to accompany Cialis with adequate and proper warnings regarding all possible adverse side effects, including serious injury (e.g., development and/or exacerbation of melanoma) associated with the use of the same and instructions on ways to safely use Cialis to avoid injury;

o. failing to use due care in the manufacture, inspection, and

labeling of Cialis to prevent the aforementioned risk of injuries to individuals who used the drug;

p. failing to use due care in the promotion of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

q. failing to use due care in the sale and marketing of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

r. failing to use due care in the selling of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Cialis;

u. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such

reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;

v. failing to educate healthcare providers, patients, and the public about the safest use of the drug;

w. failing to give patients and healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

x. being otherwise reckless, careless and/or negligent.

96. Despite the fact that Defendant knew or should have known that Cialis increased the risk of serious injury and/or death, Defendant continued to promote and market Cialis to doctors and to consumers, including Plaintiff, when safer and more effective methods of treatment were available.

97. As a direct and proximate result of the negligence committed by Defendant in testing and ultimately selling Cialis, Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

98. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the

costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT V
(Gross Negligence)

99. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

100. Defendant had a duty to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Cialis, including a duty to ensure that Defendant's product, Cialis, did not cause users to suffer from unreasonable and dangerous side effects.

101. Defendant failed to exercise reasonable care in the warning about, design, testing, manufacture, marketing, labeling, sale, and/or distribution of Defendant's product, Cialis, in that Defendant knew or should have known that taking Cialis caused unreasonable and life-threatening injuries, as alleged herein.

102. Defendant was grossly negligent under the circumstances and breached its duty of care in numerous ways, including the following:

a. failing to test Cialis properly and thoroughly before releasing the drug to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of Cialis;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Cialis which indicated risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of Cialis;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing, and selling Cialis to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Cialis and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

g. failing to exercise due care when advertising and promoting Cialis;

h. recklessly continuing to manufacture, market, advertise, and distribute Cialis after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. failing to use due care in the preparation and development of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

j. failing to use due care in the design of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of Cialis;

l. failing to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Cialis, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Cialis for causing serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to withdraw it from the market altogether;

m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-

marketing surveillance and testing to Plaintiff, his doctors, other consumers, the medical community, and the FDA;

n. failing to accompany Cialis with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. failing to use due care in the manufacture, inspection, and labeling of Cialis to prevent the aforementioned risk of injuries to individuals who used the drug;

p. failing to use due care in the promotion of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

q. failing to use due care in the sale and marketing of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

r. failing to provide adequate and accurate training and information to the sales representatives who sold the drug;

s. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of Cialis;

t. failing to conduct or fund research into the development of medications of this type which would pose the least risk of causing such serious injury and death, as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and into the development of better remedies and treatment for those who experience these tragic adverse reactions;

u. failing to educate healthcare providers and the public about the safest use of the drug;

v. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

w. was otherwise grossly negligent.

103. Although Defendant knew, or recklessly disregarded, the fact that Defendant's product, Cialis, caused serious and potentially fatal side effects, Defendant continued to market Cialis to consumers, including Plaintiff, without disclosing these side effects including the risks of serious injury and/or death.

104. Defendant knew and/or consciously or recklessly disregarded the fact that consumers such as Plaintiff would suffer injury as a result of Defendant's failure to exercise reasonable care as described above.

105. Defendant knew of, or recklessly disregarded the defective nature of Defendant's product, Cialis, as set forth herein, but continued to design, manufacture, market, and sell Cialis, so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or reckless disregard of the foreseeable harm caused by Cialis.

106. As a direct and proximate result of Defendant's gross negligence, Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

107. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VI
(Negligence Per Se)

108. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

109. At all times herein mentioned, Defendant had an obligation not to violate the law, including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the manufacture, design, formulation, compounding, testing, production, processing, assembling, inspection, research, promotion,

advertising, distribution, marketing, labeling, packaging, preparation for use, consulting, sale, warning, and post-sale warning and other communications of the risks and dangers of Cialis.

110. By reason of its conduct as alleged herein, Defendant violated provisions of statutes and regulations, including, but not limited to, the following:

a. Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352, by misbranding Cialis;

b. Defendant failed to follow the "[g]eneral requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.56;

c. Defendant failed to follow the "[s]pecific requirements on content and format of labeling for human prescription drugs" in violation of 21 C.F.R. § 201.57; and

d. Defendant advertised and promoted Cialis in violation of 21 C.F.R. § 202.1; and

e. Defendant violated 21 C.F.R. § 201.57(e) by failing to timely and adequately change the Cialis label to reflect the evidence of an association between Cialis and the development and/or exacerbation of melanoma suffered by Plaintiff.

These statutes and regulations impose a standard of conduct designed to protect consumers of drugs, including Plaintiff. Defendant's violations of these statutes and regulations constitute negligence per se.

111. As a direct and proximate result of Defendant's statutory and regulatory violations, Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

112. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VII
(Breach of Express Warranty)

113. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

114. At all times relevant hereto, Defendant expressly represented and warranted to Plaintiff and his healthcare providers, by and through statements made by Defendant or its authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients, and the general public, that Cialis is safe, effective, and proper for its intended use.

115. Defendant breached expressed warranties with respect to Cialis in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Cialis was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using Cialis;

b. Defendant represented that Cialis was as safe, and/or safer than other alternative medications and fraudulently concealed information that demonstrated that Cialis was not safer than alternatives available on the market; and

c. Defendant represented that Cialis was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drug.

116. Cialis does not conform to Defendant's express representations because its mechanism of action, the inhibition of the PDE5 enzyme, also increases the risk of the development and/or exacerbation of melanoma.

117. At all relevant times, Cialis did not perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.

118. Plaintiff, Plaintiff's physicians, other consumers, and the medical community relied upon Defendant's express warranties, resulting in Plaintiff's ingestion of the drug.

119. As a direct and proximate result of the breach of warranty committed by Defendant, Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

120. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT VIII
(Breach of Implied Warranty)

121. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

122. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold Cialis.

123. At all relevant times, Defendant intended that Cialis be used in the manner that Plaintiff in fact used it.

124. Defendant impliedly warranted Cialis to be of merchantable quality, safe and fit for the use for which Defendant intended it, and Plaintiff in fact used it.

125. Defendant was aware that consumers, including Plaintiff, would use Cialis to achieve and maintain an erection; which is to say that Plaintiff was a foreseeable user of Defendant's product Cialis.

126. Defendant knew, or had reason to know, that Plaintiff's physician would rely on Defendant's judgment and skill in providing Cialis for its intended use.

127. Plaintiff and his physician reasonably relied upon the skill and judgment of Defendant as to whether Cialis was of merchantable quality, safe and fit for its intended use.

128. The drug was expected to reach and did in fact did reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.

129. Defendant breached various implied warranties with respect to Cialis including the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Cialis was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using Cialis;

b. Defendant represented that Cialis was as safe, and/or safer than

other alternative medications and fraudulently concealed information that demonstrated that Cialis was not safer than alternatives available on the market; and

c. Defendant represented that Cialis was more efficacious than other alternative medications and fraudulently concealed information regarding the true efficacy of the drug.

130. In reliance upon Defendant's implied warranty, Plaintiff used Cialis as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

131. Cialis was neither safe for its intended use nor of merchantable quality, as had been implicitly warranted by Defendant, in that Cialis's mechanism of action, the inhibition of PDE5, inherently presented a significant increase in the user's risk of developing and/or exacerbating melanoma.

132. Defendant breached its implied warranty to Plaintiff in that Cialis is unreasonably dangerous, defective, and unfit for the ordinary purposes for which Cialis was used. It was not of merchantable quality, safe and fit for its intended use, or adequately tested.

133. As a direct and proximate result of the falsity of the warranties implicated by Defendant's actions and omissions, Plaintiff suffered significant

pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

134. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT IX

(Fraudulent Misrepresentation and Concealment)

135. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

136. Defendant intentionally and fraudulently misrepresented to consumers and physicians, including Plaintiff, Plaintiff's physicians, and the public in general, that Cialis had been tested and found to be safe, well-tolerated and/or more efficacious than alternative medications and/or methods of erectile dysfunction therapy and that Cialis's benefits outweighed its risks when used as instructed, when, in fact, Defendant knew, or should have known, and fraudulently concealed that Cialis is dangerous to patients and that the benefits of its use are far outweighed by the risks for Plaintiff and many others.

137. At all relevant times, Defendant knew of the use for which Cialis was intended and expressly and/or impliedly warranted its drug was of merchantable quality and safe and fit for such use.

138. Defendant had sole access to material facts concerning the dangers and unreasonable risks of Cialis.

139. Defendant's superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the risks and dangers of Cialis and its intentional dissemination of promotional and marketing information about Cialis for the purpose of maximizing its sales, each gave rise to the affirmative duty to meaningfully disclose and provide all material information about the risks and harms associated with the drug.

140. Defendant made false affirmative representations, omissions and/or fraudulently concealed material adverse information regarding the dangers, risks, safety, benefits, utility and effectiveness of Cialis in order to induce Plaintiff, Plaintiff's physicians, and the public in general to rely upon such representations and to use Cialis. By failing to disclose important safety and injury information and suppressing material facts about Cialis to Plaintiff, Plaintiff's physicians, and the public in general, Defendant further led Plaintiff and Plaintiff's physicians to rely upon the safety of Cialis.

141. Defendant had a duty to disclose such information, arising from Defendant's actions of making, marketing, promoting, labeling, distributing and selling pharmaceutical products to Plaintiff and others.

142. Defendant's false representations and concealments were fraudulently made, in that Cialis in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

143. Defendant committed acts of intentional misrepresentation and intentional concealment by suppressing material facts relating to the dangers and substantial risks of serious injuries and/or death associated with, and caused by, the use of Cialis.

144. Defendant made such false representations, omissions and concealments with the intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading to the use of Cialis by Plaintiff.

145. Defendant made fraudulent affirmative misrepresentations and omissions and fraudulent concealments of material facts regarding the safety and effectiveness of Cialis and of the dangers and risks of injuries associated with Cialis, including:

a. Defendant fraudulently represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Cialis

had been adequately tested and found to be safe and effective for erectile dysfunction, and fraudulently concealed information about the substantial risks of serious injury and/or death associated with using Cialis; and

b. Defendant fraudulently represented that Cialis was as safe and/or safer and/or more efficacious than other alternative erectile dysfunction therapies, and fraudulently concealed information that demonstrated that Cialis was not safer and/or more efficacious than alternatives available on the market.

146. Defendant knew, had reason to know, or should have known, that these representations and actively concealed adverse information were false, and that Cialis had defects and was unreasonably dangerous. Yet, Defendant willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of Cialis to consumers, including Plaintiff, and to the medical community.

147. Defendant did not have adequate proof upon which to base such representations, and in fact, given Defendant's knowledge about Cialis's pharmacology and reported adverse events, Defendant knew, or should have known, that these representations, omissions and/or concealments were false and fraudulent. Specifically, Defendant knew of, possessed evidence and/or had reason

to know that Cialis had defects and was unreasonably dangerous, causing the development and/or exacerbation of melanoma, as detailed herein.

148. Defendant's misrepresentations were made with the intent that physicians and patients, including Plaintiff, would rely upon them and were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Cialis.

149. Plaintiff, Plaintiff's physicians, and others, did rely upon and/or were induced by the misrepresentations, omissions and/or active concealment of the dangers of Cialis to the detriment of the Plaintiff.

150. Defendant's fraudulent representations and concealments evince its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

151. In selecting treatment, Plaintiff's physicians and Plaintiff relied on and were induced by Defendant's misrepresentations concerning the dangers of Cialis.

152. As detailed herein, Defendant made these fraudulent misrepresentations, omissions and concealments through statements and comments to the press, labeling, advertising, marketing and promotion materials, seminar presentations, publications, Dear Doctor letters, and regulatory submissions.

153. Plaintiff and the treating medical community did not know that the representations, omissions, and/or concealments made by Defendant were false and were justified in reasonably relying upon Defendant's representations.

154. Had Defendant not fraudulently misrepresented and concealed such information, Plaintiff would not have ingested Cialis and suffered resulting harm.

155. Defendant made the aforesaid representations and concealments intentionally and in the course of Defendant's business as designers, manufacturers, and distributors of Cialis despite having no reasonable basis for the assertion that these representations were true, without having accurate or sufficient information concerning the aforesaid representations and/or knowing these representations were false. Defendant was aware that without such information it could not accurately make the aforesaid representations.

156. At the time Defendant made the aforesaid representations and at the time Plaintiff received Cialis, Plaintiff, Plaintiff's physicians, and the public in general reasonably believed them to be true. At the time that Plaintiff received Cialis, Defendant failed to adequately inform Plaintiff and/or his prescribing doctors that Cialis use increased the risk of the development and/or exacerbation of melanoma, despite Defendant being in possession of such evidence. Plaintiff received no adequate warnings, either written or verbal, that Cialis caused these side effects, and relied on these omissions and concealments.

157. As a direct and proximate consequence of Defendant's fraudulent misrepresentations, omissions, and intentional concealment of material facts, upon which Plaintiff reasonably relied, Plaintiff sustained significant pain, injury, harm, suffering, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

158. **WHEREFORE**, Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT X
(Negligent Misrepresentation and Concealment)

159. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

160. At all relevant times, Defendant designed, tested, manufactured, packaged, marketed, distributed, promoted, and sold Cialis.

161. At all relevant times, Defendant knew of the use for which Cialis was intended and expressly and/or impliedly warranted that the drug was of merchantable quality and safe and fit for such use.

162. Defendant's superior knowledge and expertise, its relationship of trust and confidence with doctors and the public, its specific knowledge regarding the

risks and dangers of Cialis, and its intentional dissemination of promotional and marketing information about Cialis for the purpose of maximizing its sales, each gave rise to the affirmative duty to disclose and provide all material information about the risks and harms associated with the drug.

163. Defendant recklessly, and/or negligently represented to Plaintiff, Plaintiff's physicians, and other persons and professionals whom Defendant knew would rely, that Cialis was safe to ingest and that the utility of this product outweighed any risk in use for their intended purposes.

164. Defendant recklessly and/or negligently failed to disclose to Plaintiff, and others, important safety and efficacy information, thereby suppressing material facts about the drug, while having a duty to disclose such information, which duty arose from its actions of making, marketing, promoting, distributing and selling pharmaceutical products to Plaintiff and others.

165. Defendant led Plaintiff to rely upon the safety of the product in its use.

166. The false representations of the Defendant were recklessly and/or negligently made in that Cialis in fact caused injury, was unsafe, and the benefits of its use were far outweighed by the risk associated with use thereof.

167. Defendant committed acts of reckless and/or negligent misrepresentation and reckless and/or negligent concealment by suppressing

material facts relating to the dangers and injuries associated with, and caused by, the use of Cialis.

168. Defendant knew or should have known that its representations and/or omissions were false. Defendant made such false, negligent and/or reckless representations with the intent or purpose that Plaintiff and Plaintiff's physicians would rely upon such representations, leading to the use of Cialis by Plaintiff.

169. Defendant recklessly and/or negligently misrepresented, and/or omitted information with respect to Cialis in the following particulars:

a. Defendant represented through its labeling, advertising, marketing materials, seminar presentations, publications, notice letters, and regulatory submissions that Cialis was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using Cialis;

b. Defendant represented that Cialis was as safe and/or safer than other alternative erectile dysfunction therapies and fraudulently concealed information, which demonstrated that Cialis was not safer than alternatives available on the market; and

c. Defendant represented that Cialis was more efficacious than other alternative erectile dysfunction therapies and fraudulently concealed information, regarding the true efficacy of the drug.

170. Defendant made affirmative misrepresentations and recklessly and/or negligently omitted material adverse information regarding the safety and effectiveness of Cialis.

171. Defendant made these misrepresentations and/or omissions at a time when Defendant knew or had reason to know that Cialis had defects and was unreasonably dangerous and was not what Defendant had represented to the medical community, the FDA and the consuming public, including Plaintiff.

172. Defendant omitted, suppressed, and/or concealed material facts concerning the dangers and risk of injuries associated with the use of Cialis including, serious injury and death. Furthermore, Defendant was willfully blind to, ignored, downplayed, avoided, and/or otherwise understated the serious nature of the risks associated with the use of Cialis in order to increase sales.

173. Defendant's misrepresentations and/or omissions were undertaken by Defendant with an intent that doctors and patients, including Plaintiff, rely upon them.

174. Defendant's misrepresentations and/or omissions were undertaken with the intent of defrauding and/or deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of Cialis.

175. Defendant's misrepresentations and/or omissions evinced the Defendant's callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

176. Plaintiff's physician and Plaintiff relied on and were induced by Defendant's misrepresentations, omissions, and/or active concealment of the dangers of Cialis in selecting treatment.

177. Plaintiff and Plaintiff's physicians did not know that the representations made by Defendant were false and were justified in relying upon Defendant's representations.

178. Had Plaintiff been aware of the increased risk of side effects associated with Cialis and the relative efficacy of Cialis compared with other readily available alternative erectile dysfunction therapies, Plaintiff would not have taken Cialis.

179. As a direct and proximate consequence of Defendant's misrepresentations, Plaintiff sustained injuries and damages alleged herein including specifically those alleged herein.

180. Plaintiff relied on the misrepresentations made by Defendant in purchasing and using Cialis.

181. Plaintiff's reliance on Defendant's misrepresentations was justified because such misrepresentations were made by entities that were in a position to

know of and disclose any potentially harmful information concerning the use of Cialis.

182. If Plaintiff had known of the information concealed by Defendant regarding the melanoma-related risks posed by Cialis, Plaintiff would not have purchased and subsequently used Cialis.

183. As a direct and proximate result of the negligent misrepresentations by Defendant, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

184. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT XI
(Fraud and Deceit)

185. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

186. At all times relevant hereto, Defendant conducted a sales and marketing campaign to promote the sale of Cialis and willfully deceive Plaintiff, Plaintiff's healthcare providers, and the general public as to the benefits, health risks, and consequences of using Cialis.

187. While conducting its sales and marketing campaign, Defendant knew that Cialis is neither safe nor fit for human consumption; that using Cialis is hazardous to health; and that Cialis has a propensity to cause serious injuries, such as those suffered by Plaintiff.

188. From the time the company first marketed and distributed Cialis until the present, Defendant willfully deceived Plaintiff by concealing from him, his healthcare providers, and the general public the risks and dangers concerning the use of Cialis.

189. Plaintiff and Plaintiff's health care providers reasonably relied upon these misrepresentations and omissions of material fact to Plaintiff's detriment.

190. Defendant intentionally concealed and suppressed the facts concerning Cialis's melanoma-related risks with the intent to defraud potential consumers, as Defendant knew that healthcare providers would not prescribe Cialis, and consumers like Plaintiff would not use Cialis, if they were aware of the dangers posed by using Cialis.

191. As a direct and proximate result of Defendant's fraudulent and deceitful conduct, Plaintiff suffered significant pain, injury, suffering, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

192. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT XII
(Willful, Wanton, Oppressive, Fraudulent, and Malicious Conduct)

193. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

194. Defendant directly or indirectly, maliciously and wantonly made, created, manufactured, designed, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold Cialis.

195. Defendant breached its duty and was willful, wanton, oppressive, fraudulent, and malicious in its actions, misrepresentations, and omissions in that it:

a. failed to test Cialis properly and thoroughly before releasing the drug to the market;

b. failed to analyze properly and thoroughly the data resulting from the pre-marketing tests of Cialis;

c. failed to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of Cialis which indicated risks associated with its use;

d. failed to conduct adequate post-market monitoring and surveillance of Cialis;

e. failed to conduct adequate analysis of adverse event reports;

f. designed, manufactured, marketed, advertised, distributed, and sold Cialis to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Cialis and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;

g. failed to exercise due care when advertising and promoting Cialis;

h. willfully and wantonly continued to manufacture, market, advertise, and distribute Cialis after Defendant knew or should have known of the risks of serious injury and/or death associated with using the drug;

i. willfully and wantonly failed to use due care in the preparation and development of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

j. willfully and wantonly failed to use due care in the design of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

k. failed to conduct adequate pre-clinical testing and research to determine the safety of Cialis;

l. failed to conduct adequate post-marketing surveillance and exposure studies to determine the safety of Cialis, while Defendant knew or should have known that post-marketing surveillance would be the only means to determine the relative risk of Cialis for causing such serious injury and death as alleged herein in the absence of clinical trials, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the drug's warnings or to withdraw it from the market altogether;

m. failed to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing and post-marketing surveillance and testing to Plaintiff, Plaintiff's physicians, other consumers, the medical community, and the FDA;

n. failed to accompany Cialis with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. willfully and wantonly failed to use due care in the manufacture, inspection, and labeling of Cialis to prevent the aforementioned risk of injuries to individuals who used the drug;

p. willfully and wantonly failed to use due care in the promotion of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

q. willfully and wantonly failed to use due care in the sale and marketing of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

r. willfully and wantonly failed to use due care in the selling of Cialis to prevent the aforementioned risk of injuries to individuals when the drug was ingested;

s. failed to provide adequate and accurate training and information to the sales representatives who sold the drug;

t. failed to provide adequate and accurate training and information to healthcare providers for the appropriate use of Cialis;

u. failed to conduct or fund research into the development of medications of this type which would pose the least risk of causing serious injury and death as alleged herein, into the early detection of persons who might be most susceptible to such reactions, and

into the development of better remedies and treatment for those who experience these tragic adverse reactions;

v. failed to educate healthcare providers and the public about the safest use of the drug;

w. failed to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient; and

x. otherwise behaved willfully, wantonly, and maliciously.

196. Defendant knew or should have known that Cialis was unreasonably dangerous and could cause serious injuries, including death.

197. As a direct and proximate result of the willful, wanton, oppressive, fraudulent, and malicious acts and omissions of Defendant, the Plaintiff sustained injuries and damages alleged herein.

198. As a direct and proximate result of Defendant's willful, wanton and malicious conduct, Plaintiff suffered significant pain, injury, and economic damages incurred through cancer treatment from melanoma caused by Cialis use.

199. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT XIII
(Unjust Enrichment)

200. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

201. At all times relevant to this action, Defendant designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold Cialis.

202. Plaintiff purchased Cialis for the purpose of achieving and maintaining an erection.

203. Defendant has accepted payment from Plaintiff for the purchase of Cialis.

204. Plaintiff did not receive the safe and effective pharmaceutical product for which Plaintiff intended to purchase.

205. It is inequitable and unjust for Defendant to retain this money because the Plaintiff did not in fact receive the product Defendant represented Cialis to be.

206. Based on the foregoing, Plaintiff is entitled to equitable relief against Defendant on account of its unjust enrichment.

207. **WHEREFORE,** Plaintiff demands judgment against Defendant and seeks damages as detailed in the Global Prayer for Relief including: compensatory damages, exemplary damages, and punitive damages, together with interest, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

COUNT XIV
(Violation of Unfair Trade Practice Act)

208. Plaintiff adopts and incorporates all preceding paragraphs as if stated fully herein.

209. By reason of the conduct as alleged herein, and by inducing Plaintiff to use and Plaintiff's physicians to prescribe Cialis through the use of deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices, and the concealment and suppression of material facts including, but not limited to, fraudulent statements, concealments, and misrepresentations identified herein and above, Defendant violated state and federal unfair trade practice laws.

210. As a direct and proximate result of Defendant's statutory violations, Plaintiff was damaged by Cialis which would not have occurred had Defendant not used deception, fraud, false advertising, false pretenses, misrepresentations, unfair and/or deceptive practices, and the concealment and suppression of material facts to induce Plaintiff to use and Plaintiff's physicians to prescribe this product.

211. By reason of such violations, Plaintiff is entitled to recover all of the monies paid for Cialis; to be compensated for the cost of the medical care arising out of the use of Cialis; and to recover any and all consequential damages recoverable under the law including, but not limited to, both past and future medical expenses, past and future pain, suffering, and emotional distress. Plaintiff

is entitled to seek compensatory damages, attorney's fees, and other remedies as determined by the Court.

PUNITIVE DAMAGES

212. Prior to the manufacturing, sale, and distribution of Cialis, Defendant knew that said medication was in a defective condition as previously described herein, and knew that those who were prescribed the medication would experience and had already experienced severe physical, mental, and emotional injuries.

213. Defendant, through its officers, directors, managers, and agents, knew that Cialis presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and, as such, Defendant unreasonably subjected consumers of said drugs to risk of injury or death from using Cialis.

214. Defendant and its agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of Cialis knowing these actions would expose persons to serious danger in order to advance the company's market share and profits.

215. The acts, conduct, and omissions of Defendant, as alleged throughout this Complaint, were malicious, willful, wanton, oppressive, fraudulent, and grossly negligent.

216. Defendant's unconscionable conduct warrants an award of exemplary and punitive damages against the company.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays judgment against Defendant as follows:

A. Declare, adjudge and decree the conduct of Defendant as alleged herein to be unlawful;

B. Actual, compensatory, punitive and/or exemplary damages in such amount to be determined at trial and as provided by applicable law;

C. Costs of suit, including reasonable attorneys' fees, and expenses as provided by law; and

D. Other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

DEMAND FOR JURY TRIAL

Plaintiff Ralph T. Motes, Jr. demands a trial by jury.

Dated: August 23, 2016.

Respectfully submitted,

/s/ B. Kristian Rasmussen

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JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

RALPH T. MOTES, JR.

(b) County of Residence of First Listed Plaintiff Wakulla County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
Cory Watson, P.C.: 2131 Magnolia Avenue South, Birmingham, AL 35205; (205)328-2200

DEFENDANTS

ELI LILLY AND COMPANY

County of Residence of First Listed Defendant Marion, IN
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question (U.S. Government Not a Party)
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excl. Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury

PERSONAL INJURY
- ❒ 362 Personal Injury - Med. Malpractice
- ☒ 365 Personal Injury - Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 444 Welfare
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 440 Other Civil Rights

PRISONER PETITIONS
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition

FORFEITURE/PENALTY
- ❒ 610 Agriculture
- ❒ 620 Other Food & Drug
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 630 Liquor Laws
- ❒ 640 R.R. & Truck
- ❒ 650 Airline Regs.
- ❒ 660 Occupational Safety/Health
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 730 Labor/Mgmt.Reporting & Disclosure Act
- ❒ 740 Railway Labor Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TAX SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 490 Cable/Sat TV
- ❒ 810 Selective Service
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 875 Customer Challenge 12 USC 3410
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 892 Economic Stabilization Act
- ❒ 893 Environmental Matters
- ❒ 894 Energy Allocation Act
- ❒ 895 Freedom of Information Act
- ❒ 900Appeal of Fee Determination Under Equal Access to Justice
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from another district (specify) ❒ 6 Multidistrict Litigation ❒ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
28 U.S.C. 1332

Brief description of cause:
Product Liability

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
08/23/2016

SIGNATURE OF ATTORNEY OF RECORD
/s/ Kristian Rasmussen

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of Florida

RALPH T. MOTES, JR.

Plaintiff(s)

v.

ELI LILLY AND COMPANY

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* ELI LILLY AND COMPANY
NATIONAL REGISTERED AGENTS, INC.
150 WEST MARKET STREET, SUITE 800
INDIANAPOLIS, IN 46204, USA

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Kristian Rasmussen
Cory Watson, P.C.
2131 Magnolia Avenue South
Birmingham, AL 35205
205-328-2200

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 08/23/2016

Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: